K070614/S1
P1/5

5. 510(K) SUMMARY

General Information

MAY - 4 2007

5.1 APPLICANT

Date:

Name: Viasys Healthcare GmbH

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in the U.S.:	**Yvette Lloyd**
Address	Viasys Respiratory Care - YL 22705 Savi Ranch Parkway Yorba Linda, CA 92887-4668
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Contact person in Germany:	**Detlef Grotheer**
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Signature:

5.2 TRADE NAME

CorScreen

5.3 Common Name or Classification Name

ECG Interpretive Electrocardiograph

5.4 Establishment Registration Number

9615102

5.5 Facility Address

Viasys Healthcare GmbH
Leibnizstrasse 7
D-97204 Hoechberg
Germany

5.6 Device Classification

5.6.1 Classification

This is a class II device

5.6.2 Classification panel

Panel: Circular System Devices Panel (74), ECG
Product Code DPS

5.6.3 Regulation Number0

870.2340

5.7 Reason for Premarket Notification

Approval of new ECG-device and interpretive software in combination with existing monitor (Viasys Flowscreen, K932744)

5.8 Predicate Devices Descriptions

5.8.1 Name

AB CARDIETTE Daedalus View Hes

5.8.2 Predicate Device Company

H&C Medical Devices spa
Italy

5.8.3 Predicate Device 510(k)#

K002074

5.9 Device Description

CorScreen is an electrocardiograph providing the following characteristics:

- Mains operation
- Simultaneous acquisition of the 12 standard leads
- Colour LCD display for user interface and ECG visualisation
- Alphanumerical keyboard
- Colour ink-printer for printouts of ECG and interpretation reports in US-letter and DIN A4 size
- Digital filters for base-line drift and mains interference suppression
- Interpretation program Hanover ECG System (HES) providing the following additional information:
  - Representatives templates of each lead including markers on fiducial points
  - Summary of mean measurements
  - Summary of measurements performed on each lead
  - Rhythm Analysis Statements
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements

- QRS T Diagnostic statements
- Arrhythmia monitoring detection
- Heart Rate Variability

- Storage of 10 seconds of acquired ECG signal
- Patient information and ECGs are stored in an internal database
- Data can be stored on an SD memory card

Promotional material and "Instructions for Use" are submitted as annex A and annex B.

5.10 Intended Use Statement

CorScreen is an active medical device and is intended for measuring a 3/6- or 12-channel surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. 12-channel ECGs are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be made by the software.

CorScreen can be used for non interpretive applications for patients with an age of 4 years and older and a weight of 20 kg or higher. CorScreen is intended for use in routine ECG recording by trained physicians in the office or hospital. CorScreen is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients.

The interpretation software is intended to support the physician in evaluating the ECG in terms of morphology and rhythm.

A qualified physician has to reassess all CorScreen measurements. An interpretation by CorScreen is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CorScreen represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements.

The intended use is equivalent to the intended use of the predicate device AB Cardiette Daedalus View Hes.

5.11 Required Components

- CorScreen-monitor
- CorScreen ECG-amplifier
- Disposable ECG-electrodes
- User manual

5.12 Summary Table of Comparisons

No.	Parameter	CorScreen	Predicate Device AB CARDIETTE DAEDALUS VIEW Base and Hes
1.	Intended Use	CorScreen is an active medical device and is intended for measuring a 3/6- or 12-channel surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. 12-channel ECGs are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be	AB Cardiette Daedalus View Base and Hes are two electrocardiographs characterized as follows: Daedalus View Base is a basic standard electrocardiograph. Daedalus View Hes is equivalent to the base version but provided with an additional program for automated ECG analysis.

		made by the software. CorScreen can be used for non interpretive applications for patients with an age of 4 years and older and a weight of 20 kg or higher. CorScreen is intended for use in routine ECG recording by trained physicians in the office or hospital. CorScreen is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients. The interpretation software is intended to support the physician in evaluating the ECG in terms of morphology and rhythm. A qualified physician has to reassess all CorScreen measurements. An interpretation by CorScreen is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CorScreen represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements.	Intended use is equivalent to the intended use of the predicate Interp 1000. More specifically: both equipments are intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and can be visualized on a digital display and recorded on thermal paper. Intended use for non interpretive applications (both versions View Base and Hes) cover the full range of patient population with no limitations with respect to age, sex, and race of the patient. The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rhythm and morphology.
2.	ECG interpretation software	Based on Hes (Hanover ECG System) Among other features: Representatives templates on each lead including markers on fiducial points	Based on Hes (Hanover ECG System) Among other features: Representatives templates on each lead including markers on fiducial points
3.	Input dynamic range	+/- 300mV @ DC	+/-300mV @ DC
4.	Frequency response bandwidth	0,05-150Hz / according to EC11 and IEC 60601-2-51	0,05 – 150 Hz
5.	A/D conversion	24 bits	14 bits
6.	Leads	12 Standard	12Standard / 12 Cabrera
7.	Paper Speed	25, 50 mm/s +/-5% According to EC11	1.25 2.5 5 10 12.5 mm/s +/-5%
8.	Recorder Sensitivity	5, 10 , 20 mm/mV According to EC11	1.25 2.5 5 10 20 40 mm/mV
9.	Writing System	Ink-printer US-letter and DIN-A4 size	Thermal head 210 mm 8 dots/mm

10.	Printed Channels	1/2/6/12	3/4/6/12
11.	Paper	US-Letter and DIN-A4	Thermal Paper DOTCARD 210mm
12.	Mode of operation	Manual	Manual, Manual delayed and Automatic recording
13.	Input/output	SD Memory card	RS232 standard digital port
14.	**Display**		
15.	Size	320 x 240 pixels	VGA 640 x 480 pixels
16.	N° of displayed channels	1/3/6/12	3/6
17.	Traced speeds	5 10 25 50 mm/s	1.25 2.5 5 10 12.5 25 50 mm/s
18.	Sensitivity	5 10 20 40 mm/mV	1.25 2.5 5 10 20 40 mm/mV

The differences in technological characteristics between CorScreen and the predicate device AB CARDIETTE View Base and Daedalus View Hes can be summarized as follows:

- Use of an external ECG-amplifier / analog-digital converter instead of an internal
- Use of an ink-printer versus thermal printer
- Data can be stored on an SD memory card
- CorScreen has four different sensitivities of the recorder, compared to six different sensitivities of the predicate device. This is not relevant for safety and effectiveness, because the two missing low sensitivities would lead to a compressed ECG signal (height). These signals would be more difficult to read.
- CorScreen has four different trace speeds instead of seven speeds. This is not relevant for safety and effectiveness, because the two missing low speeds lead to highly compressed ECG-recordings that are difficult to read. This is only an issue for saving paper.
- The CorScreen display is smaller than the display of the predicate device. This is not relevant for safety and effectiveness, because diagnosis is intended to be performed by means of the paper report produced by the CorScreen. The display is used only for controlling the ECG-measurement process and is therefore sufficient for the intended use.

5.13 Summary of Device Testing

Both devices, CorScreen and the predicate device AB CARDIETTE View Base and Daedalus View Hes, have been tested according to EN 60601-1 and IEC 601-2-25. Furthermore, CorScreen has been tested according to the standards listed in chapter 9 of this 510(k) and has shown full compliance to the standards.

5.14 Conclusions

Based on the above, VIASYS HEALTHCARE GMBH concludes, that CorScreen is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2007

Viasys Respiratory Care – YL
c/o Yvette Lloyd
Senior Regulatory Affairs Specialist
22705 Savi Ranch Parkway
Yorba Linda, CA 92887-4668

Re: K070614
Trade/Device Name: CorScreen
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 24, 2007
Received: April 27, 2007

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070614/S1

Indications for Use

510(k) Number (if known): K070614

Device Name: CorScreen

Indications for Use:

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Federal U.S. law restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vo-Nuyen

(Division Sign-Off)
Division of Cardiovascular Devices

5 (K) Number K070614